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Implementation of locally adapted guidelines on type 2 diabetes

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Objective. To assess the effects of a facilitator enhanced multifaceted intervention to implement a locally adapted guideline on the shared care for people with type 2 diabetes.

Methods. During 1 year a cluster-randomized trial was performed in 30 general practices. In the intervention group, nurse facilitators enhanced guideline implementation by analysing barriers to change, introducing structured care, training practice staff and giving performance feedback. Targets for HbA1c%, systolic blood pressure as well as indications for angiotensin converting enzyme/angiotensin receptor blocking agent prescription differed from the national guidelines. In the control group, GPs were asked to continue the care for people with diabetes as usually. Generalized estimating equations were used to control for the clustered design of the study.

Results. In the intervention group, more people were seen on a 3-monthly basis (88% versus 69%, $P < 0.001$) and more blood pressure and bodyweight measurements were performed every 3 months (blood pressure 83% versus 66%, $P < 0.001$ and bodyweight 78.9% versus 48.5%, $P < 0.001$). Apart from a marginal difference in mean cholesterol, differences in HbA1c%, blood pressure, body mass index and treatment satisfaction were not significant.

Conclusion. Multifaceted implementation of locally adapted shared care guidelines did improve the process of diabetes care but hardly changed intermediate outcomes. In the short term, local adaptation of shared care guidelines does not improve the cardiovascular risks of people with type 2 diabetes.

Keywords. Chronic disease management, diabetes, randomized controlled trial.

Introduction

Clinical practice guidelines are considered effective tools to improve the quality of diabetes care.[1] Their implementation, however, has not been straightforward. It has become evident that passive dissemination of guidelines is largely ineffective and only rarely induces a behavioural change.[2] Successful implementation strategies, therefore, are active and targeted at different levels of care (professional, team, patient and organization).[3] Such strategies must be adequately resourced and include systems for training and evaluation.[4] Recently, a Cochrane review concluded that multifaceted interventions can improve the treatment of people with diabetes, as can organizational interventions that improve the recall and tracking of these people.[5] In general, multifaceted interventions targeting different barriers to change are more likely to be effective than single interventions.[6] Furthermore, physician support and feedback by trained facilitators proved to be helpful in improving glycaemic control[7] and appeared to increase the rates of foot and eye examination in general practice.[8] Finally, it has been suggested that end-user involvement in the development and adaptation of national guidelines can result in an increased uptake.[9] A systematic review suggested that the use of a local consensus process was more likely to lead to the effective implementation of clinical guidelines.[10] A more recent study, on the other hand, did not find any additional effect from the local adaptation process itself.[11] Hence, it is questionable whether local adaptation of national guidelines is an

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essential prerequisite to ensuring improvements in the quality of care.

In an effort to improve the quality of diabetes care and reduce disease-related costs, much attention is paid to different models of diabetes care like shared care, integrated care and disease management. Especially, disease management is expected to succeed were other approaches have failed. Systematic reviews support this view,[12,13] but recognize important limitations of the original studies, including lack of consensus about what constitutes disease management. In The Netherlands, much attention is paid to the concept of shared care. Physicians, nurses and paramedics are called upon to implement multidisciplinary shared care guidelines to minimize the risks for patients with chronic diseases. However, randomized controlled trials supporting this view are rare.

We report the results of a multifaceted facilitator enhanced intervention aimed at the implementation of a local guideline on the shared care for people with type 2 diabetes.

Research design and methods

The study was carried out in and around Apeldoorn, a city with 150 000 inhabitants in The Netherlands. It was a cluster-randomized trial comparing usual care with care according to locally adapted shared care guidelines, taking clustering at a practice level into account[14] The Medical Ethical Committee of the University Medical Centre Utrecht approved the protocol and all participants gave informed consent.

Study participants

We asked all primary care practices in the greater Apeldoorn region (n = 70) to participate. In the 30 participating practices, the lists of people diagnosed with type 2 diabetes were updated prior to the start of the study. For this purpose, a computer search was performed using the following terms: Anatomical Therapeutic Chemical code A10 (insulin and oral hypoglycaemic agents), International Classification of Diseases in Primary Care code T90 (diabetes) and diabetes (text word). Then, the files of all tracked people were checked for the type of diabetes. Only people with type 2 diabetes (n = 3357) were considered eligible for the present study. Exclusion criteria were the inability to complete a questionnaire, severe mental illness, unwillingness to attend the practice regularly or a limited life expectancy. As it was our aim to investigate the effect of the implementation of local shared care guidelines in primary care, people being treated at the outpatient clinic of the local hospital were excluded as well.

Randomization

Participating general practices were randomized into an intervention and control group. Prior to randomization, practices were divided into groups according to the following criteria: practice type (single handed, duo or group practice) and presence of a specialized nurse. An independent researcher then carried out a restricted randomization procedure using a random number table to ensure equal numbers of practices in each group.

Multifaceted interventions

Intervention practices were encouraged to treat people with type 2 diabetes in accordance with the locally adapted shared care guidelines. A working committee of four GPs, two internists from the local hospital, three diabetes nurse specialists and two dieticians based these guidelines on the national guidelines for the treatment of type 2 diabetes of the Dutch College of General Practitioners.[15] Due to new insights, distinct differences arose between both guidelines (Box 1). Control group practices were asked to continue the care for people with diabetes in line with the national guidelines.[15]

Box 1 *Differences between the guidelines of the Dutch College of General Practitioners and the local shared care guidelines*

Dutch College of General Practitioners guidelines	Locally adapted shared care guidelines
HbA1c >8.5% considered poor glycaemic control	**HbA1c >8%** considered poor glycaemic control
After diagnosis, all people are treated with **lifestyle intervention**. If necessary, oral hypoglycaemic agents after 3 months	After diagnosis, people with fasting blood glucose >15 mmol/l are immediately treated with **lifestyle intervention and oral hypoglycaemic agents**
Recommended blood pressure <**150**/85	Recommended blood pressure <**140**/85
Patients with life expectancy >5 years and a 10 years cardiovascular risk >**25**% are treated with statins	Patients with life expectancy >5 years and a 10 years CV risk >**20**% are treated with statins
People with microalbuminurea <**50** years are treated with angiotensin converting enzyme inhibitors	People with microalbuminurea <**60** years are treated with angiotensin converting enzyme inhibitors or ATII receptor antagonists
No rules for referral back to primary care	**Explicit** rules for referral back to primary care

In the intervention group practices, two nurse specialists interviewed practice staff, analysed barriers to change, discussed means to overcome these barriers and handed out abstracts of the guidelines on plasticized sheets. These nurses, trained as facilitators, visited all intervention practices two times per month for approximately 3 hours. During these visits, they trained the GPs, practice assistants and nurses in the use of the guidelines, encouraged the introduction of structured diabetes care, emphasized the need for 3-monthly control and gave assistance in managing people with type 2 diabetes. Performance feedback was given 6 months after the start of the intervention. We used the method described by Kiefe and others to formulate achievable benchmarks of care.[16,17] These benchmarks represent in essence the average performance for the top 10% of the physicians (practices) being assessed.

Measurements

Diabetes care providers examined all participants at the start of the study and approximately 1 year later at study completion. Demographics, duration of diabetes, smoking habits, co-morbidity and presence of macrovascular or microvascular complications were recorded. Standard operating procedures were used to record weight, height, waist and hip circumference and blood pressure. Fasting blood samples and urine samples were obtained and analyzed at the laboratory of the local hospital. HbA1c% was determined by the Variant II Turbo Haemoglobin Testing System (Bio-Rad Laboratories, Hercules, USA). Plasma glucose, total cholesterol, high density lipoprotein cholesterol, triglycerides, albumin/creatinin ratio and microalbumen were determined with the Architect ci8200SR (Abbott Park, Illinois, USA). The health-related quality of life was estimated with the EuroQol-5D (range –0.59 to 1, where 1 indicates perfect health) and the validated Dutch version of the disease-specific diabetes health profile (range 0–100, where 100 represents no dysfunction).[18,19] To describe the overall health state of the participants, we used the visual analogue scale of the EuroQol-5D (range 0–100). The satisfaction of the participants with their treatment was measured with the Dutch version of the diabetes treatment satisfaction questionnaire (range 0–36).[20]

All 18 pharmacists in the Apeldoorn region took part in our study. To obtain a complete medication file, we used their files and those of three GPs keeping their own pharmacy. We selected the complete medication histories of all participants using hypoglycaemic medication (ATC code A10) or being diagnosed by their GP with type 2 diabetes.

Statistical analysis

Three-monthly measurements of fasting blood glucose (FBG), blood pressure and bodyweight and the prescription of ATII antagonists or ACE inhibitors in case of microalbuminuria were considered to be indicators of the process of care. As primary outcome measure, we used the percentage of people with poor glycaemic control at baseline that achieved an HbA1c of $\leqslant$8%. Mean HbA1c%, total cholesterol, diastolic and systolic blood pressure, quality of life and treatment satisfaction were used as secondary outcome measurements. Participants' level of formal education was split into two categories. People who visited primary school only or primary and secondary school at a non-advanced level were considered to have a low level of formal education. All others were regarded as highly educated. Student's *t*-test and chi-square test were used where appropriate. All analyses were by intention to treat. Based on literature and clinical reasoning, we identified the following potential confounders: age, gender, level of education, micro- and macrovascular complications, insulin use and quality of life. Generalized estimating equations (GEE) models were used to construct multivariable regression models, while controlling for potential confounders and the clustered design of the study. Statistical significance was set at $P < 0.05$ two sided. Except for the GEEs, all analyses were carried out using the statistical package SPSS version 12.0 for Windows. We used SAS software version 8 (SAS Institute, Cary, NC) for the GEEs models.

Sample size calculations were based on the assumption that at baseline 30% of the participants would have an HbA1c >8.0%. A sample size of 288 would provide 80% power to detect a 30% reduction in the number of these participants. In order to adjust for clustering at practice level, we then multiplied this sample size by a design effect of 2.62 (based on an intra-class correlation coefficient of 0.034), thus requiring a total sample size of 817 people with type 2 diabetes in each study group.

Part of the participants had missing values. Ignoring cases with a missing value (complete case analysis) may lead to biased results and loss of power.[21] Therefore, we imputed missing values using the regression method available in SPSS. The imputation was based on the correlation between each variable with missing values and all other variables as estimated from the subjects with complete data.

Results

Participants

In total, 11 single handed, 16 duo and three group practices agreed to participate. Reasons for non-participation were a lack of time, a dislike of research projects, a lack of confidence in the outcome of the study and the conviction that the practice performed well and did not need improvement of diabetes care.

In 45% of the participating solo practices, specialized nurses were concerned with diabetes care; in the duo and group practices, this percentage was 56 and 67, respectively. Overall, 2983 people with type 2 diabetes were eligible. Of these people, 2042 gave informed consent. In all, 1640 participants were treated within primary care (Fig. 1).

Baseline characteristics

Except for education and the presence of macrovascular complications, patients' characteristics were highly comparable across study groups. In the intervention group, more participants had a low level of formal education. Controls were more often suffering from macrovascular complications. About 50% of the participating people with type 2 diabetes were men. Mean age of the participants was approximately 67 years (Table 1).

Process and outcome of care

After 1 year, process measures differed significantly between the intervention and the control group, except for the prescription rate of angiotensin-blocking agents and ACE inhibitors. These differences remained significant after we controlled for age, gender, level of education, micro- and macrovascular complications, insulin use, quality of life and the clustered design of the study (Table 2).

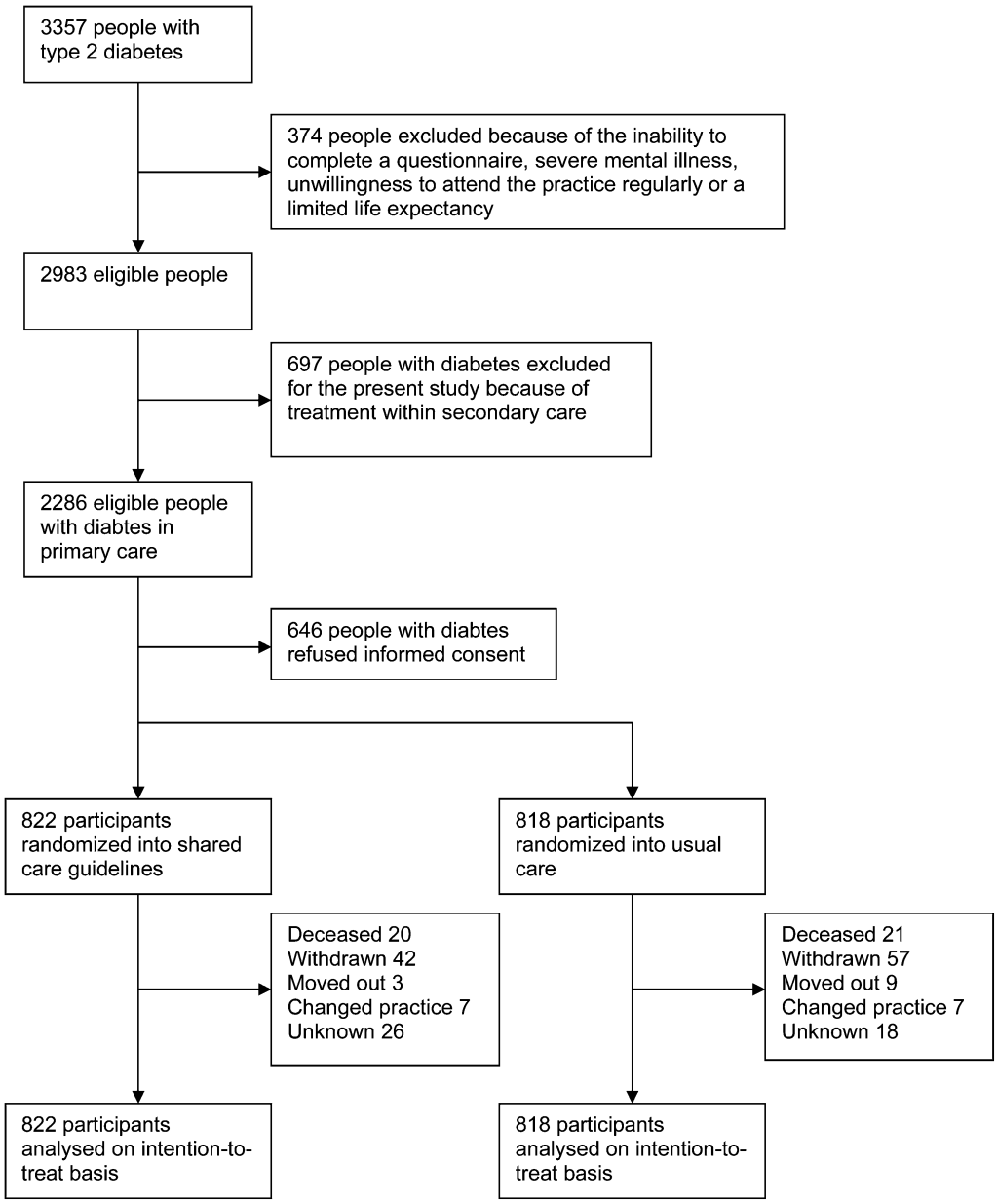

FIGURE 1 *Flow sheet of the sampling process*

In the intervention group, more initially poorly controlled participants reached adequate glycaemic control at the end of the study (70% versus 58%, $P < 0.05$). This difference became non-significant after controlling for baseline value, potential confounders and clustering at practice level. After 1 year, we were unable to demonstrate significant differences in HbA1c, blood pressure, body mass index (BMI) and treatment satisfaction between both study groups. There was, however, a small but statistically significant difference in mean cholesterol after the implementation of the locally adapted guidelines. This difference remained statistically significant after we controlled for baseline value, potential confounders and the clustered study design. At study completion, the percentages of initially poorly controlled people that reached adequate blood pressure or lipid control were equal across study groups (Tables 3 and 4).

TABLE 1 *Patient's characteristics at baseline*

	Intervention (SD), $n = 822$	Control (SD), $n = 818$
Male (%)	46.8	50.4
Age (years)	67.1 (11.4)	67.2 (11.9)
Primary school and technical school (%)	62.8	53.1
Duration of diabetes (years)	6.6 (6.0)	6.6 (5.9)
Macrovascular complication (%)	20.6	28.0
Microvascular complication (%)	6.2	8.4
Insulin use (%)	4.0	7.3
HbA1c ≤8.0% (%)	84.7	83.2
Blood pressure <140/85 mmHg (%)	22.5	26.8
Cholesterol ≤5 mmol/l (%)	42.2	46.6
HbA1c (%)	7.0 (1.1)	7.1 (1.2)
Systolic blood pressure (mmHg)	145.8 (18.4)	145.7 (20.0)
Diastolic blood pressure (mmHg)	82.5 (9.1)	82.9 (9.3)
Cholesterol (mmol/l)	5.3 (1.0)	5.2 (1.0)
BMI (kg/cm^2)	29.7 (5.6)	29.0 (5.3)
EuroQol-5D	0.81 (0.20)	0.79 (0.22)
EuroQol-VAS	76.3 (16.0)	74.3 (16.2)
DHP	85.4 (9.4)	84.4 (10.2)
DTSQ	31.8 (5.3)	31.5 (5.2)

VAS, visual analogue scale; DHP, diabetes health profile; DTSQ, diabetes treatment satisfaction questionnaire.

Barriers

The barriers most commonly identified were lack of time, lack of knowledge on the content of the guideline, lack of financial incentives, lack of motivation and reluctance to prescribe multiple drug regimens. Training practice staff on the job, organizing educational meetings and making comparisons with peers levelled these barriers. Furthermore, the nurses gave advice on insulin type and dosage in people with poor glycaemic control.

Referrals

Nearly 3% of all participants were referred to the outpatient's clinic to receive secondary diabetes care (intervention group 2.8%, control group 2.9%; $P = 0.9$). From the outpatient clinic of the local hospital, many people were referred back to primary care (24.7% versus 23.3%, $P = 0.7$).

Discussion

The facilitator enhanced implementation of a locally adapted guideline on type 2 diabetes led to a significant increase in the number of people with type 2 diabetes that were seen on a 3-monthly basis. During the intervention, bodyweights and blood pressures of the participants were also registered more often. At the end of the study, there were no significant differences in the percentages of people that reached adequate control of their diabetes, blood pressure or BMI. Mean cholesterol improved 0.1 mmol/l, while other cardiovascular risk factors remained unchanged.

Some limitations of this study need to be discussed. Firstly, as people under secondary care were excluded from this study, we are not informed about the effects of the implementation of the guidelines on the quality of secondary diabetes care. However, as randomization

TABLE 2 *Process measures in intervention and control group*

	Intervention (SD)	Control (SD)	*P*	*P**	*P***
FBG every 3 months (%)	87.8	68.6	<0.001	<0.001	<0.001
Blood pressure every 3 months (%)	82.5	65.4	<0.001	<0.001	<0.01
Bodyweight every 3 months (%)	78.9	48.5	<0.001	<0.001	<0.001
Angiotensin converting enzyme inhibitor or angiotensin receptor blocking agent prescribed according to guideline (%)	67.4	65.1	0.7	0.4	0.6

FBG, fasting blood glucose.
P: unadjusted. P*: controlled for age, gender, level of education, micro- and macrovascular complications, insulin use and quality of life. P**: controlled for age, gender, level of education, micro- and macrovascular complications, insulin use, quality of life and clustering at practice level.

TABLE 3 *Outcome measures in intervention and control group, all patients*

	Intervention (SD), n = 822	Control (SD), n = 818	P	P*	P**
HbA1c ⩽8.0% (%)	90.1	86.8	<0.05	0.07	0.1
Blood pressure <140/85 mmHg (%)	23.1	24.2	0.6	0.6	0.7
Cholesterol ⩽5 mmol/l (%)	46.4	46.0	0.9	0.3	0.3
BMI ⩽27 (%)	33.0	36.9	0.1	0.9	0.9
HbA1c (%)	6.9 (0.9)	7.0 (1.0)	<0.01	<0.05	0.1
Systolic blood pressure (mmHg)	146.3 (18.7)	146.8 (19.1)	0.6	0.4	0.9
Diastolic blood pressure (mmHg)	81.9 (9.3)	82.4 (9.7)	0.3	0.2	0.5
Cholesterol (mmol/l)	5.1 (1.0)	5.2 (1.0)	0.2	<0.01	<0.05
BMI (kg/cm^2)	29.6 (5.1)	29.0 (5.1)	<0.05	0.8	0.8
DTSQ	32.4 (4.3)	32.1 (4.4)	0.1	0.3	0.3

DTSQ, diabetes treatment satisfaction questionnaire.
P: unadjusted. P*: controlled for baseline value, age, gender, level of education, micro- and macrovascular complications, insulin use and quality of life. P**: controlled for baseline value, age, gender, level of education, micro- and macrovascular complications, insulin use, quality of life and clustering at practice level.

TABLE 4 *Percentages of initially poorly controlled people with type 2 diabetes that reached adequate control*

	Intervention (SD)	Control (SD)	P	P*	P**
HbA1c ⩽8.0% (%)	70.4 (n = 125)	57.6 (n = 139)	<0.05	0.1	0.2
Blood pressure <140/85 mmHg (%)	15.5 (n = 633)	16.4 (n = 605)	0.7	0.9	0.9
Cholesterol ⩽5 mmol/l (%)	29.7 (n = 472)	26.3 (n = 441)	0.3	0.2	0.2
BMI ⩽27 (%)	9.3 (n = 540)	8.8 (n = 501)	0.8	0.6	0.6

P: unadjusted. P*: controlled for baseline value, age, gender, level of education, micro- and macrovascular complications, insulin use and quality of life. P**: controlled for baseline value, age, gender, level of education, micro- and macrovascular complications, insulin use, quality of life and clustering at practice level.

took place within primary care, secondary care physicians were treating participants from both study groups and therefore had knowledge on the content of the guidelines. It would have been very difficult for these specialists to treat half of the participants in accordance with the local guidelines and the other half as usually. It is more likely that they would have treated all people with type 2 diabetes more or less in accordance with the local guidelines. This would most certainly have diluted the effect of our intervention. Secondly, baseline measurements were performed in the intervention as well as the control group. These measurements necessitated the recall and registration of all people with type 2 diabetes. As registration and recall are fundamental to the quality of diabetes care, their introduction may have enhanced the quality of care in the control practices. Possibly, this strategy reduced the contrast between the intervention and the control group and thus the potential to detect a positive effect of the intervention. Thirdly, when selecting people we may have missed those receiving dietary treatment only. However, as we scrutinized the medical records not only for ATC code A10 but also for ICPC code T90 and the text word diabetes, we are confident that most patients on a diet were labelled as having diabetes. Furthermore, the percentage of patients on a diet in our study was 20%. This percentage is in line with the percentages found in several other Dutch studies.[22–24] Fourthly, the sample size calculation of our study was based on the assumption that about 30% of the participants would have an HbA1c of >8%.[22] At study completion, participants' glycaemic control proved to be much better than expected. Therefore, our study might have been hampered by a lack of power. Finally, the use of a single imputation procedure may have resulted in an underestimation of the standard errors or too small P-values.[25]

The results of this study are in line with recent publications. Most large-scale quality improvement initiatives show only modest improvements in some process measures, but fail to demonstrate better intermediate or end-stage outcomes.[26] This may be illustrated by a recent study on diabetes shared care, a large-scale controlled study on the effects of the Health Disparities Collaborative and a recent study on the impact of a quality improvement intervention on the quality of diabetes care at primary care clinics.[27–29] Notwithstanding, significant improvements in diabetes care delivery none or only minor improvements in intermediate outcomes were found. A Dutch study produced more optimistic results. After the

introduction of structured shared care with task delegation to nurses, significant improvements in the process parameters and achieved target values at the individual patient level could be demonstrated.[24] However, as this was a non-randomized study, the results can only be indicative. Multiple studies have stressed the importance of local tailoring of an international or national guideline.[9,10,30–32] Local adaptation has been described as a key element in guideline implementation. However, randomized trials supporting this view are sparse. One randomized trial found significant changes in knowledge, attitude and reported practice as a result of disseminating guidelines, but it did not find any additional effect from the local adaptation process itself.[11] Our findings are in line with these results. As it was our aim to evaluate the effect of a locally adapted guideline under the best possible circumstances, we thought it unwise to enhance usual care by employing nurse facilitators in control group practices. Therefore, these facilitators gave attention to intervention group practices only. Given the fact that we were unable to demonstrate significant differences in both primary and secondary outcomes of our study, it is unlikely that local adaptation under less optimal circumstances will improve the intermediate outcomes of diabetes care.

One may wonder why our multifaceted intervention did not induce any improvement in the cardiovascular risk factors. A Danish study into structured personal diabetes care is a rare example of a randomized controlled trial showing a significant improvement in blood pressure at study completion.[33] This study lasted for 6 years, suggesting that a better outcome may follow an improved process of care over time. Clearly, the outcome of care is highly influenced by the ability of physicians to adjust the patients' regimen in time. Grant *et al.* [34] demonstrated that although the testing rates for HbA1c, blood pressure and total cholesterol in a national sample of US academic medical centres were very high, only 10.0% of this cohort met recommended goals for all three risk factors. Apparently, high rates of risk factor testing did not necessarily translate to effective metabolic control. A recent Canadian study confirmed these results: less than one-half of the people with high HbA1c levels had intensification of their medications, regardless of the specialty of their physician.[35] Failure of health care providers to initiate or intensify therapy when indicated has been called clinical inertia.[36] Clinical inertia seems to be widespread and is probably a major barrier to better diabetes care. Therefore, the results of our study may be explained, at least partially, by the failure to intensify therapy appropriately. Implementation of diabetes guidelines is likely to be more effective if energy is spent to overcome clinical inertia instead of local adaptation of nationally agreed target values, prescription rules and referral indications.

Declaration

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Ethical approval: None.
Conflicts of interests: None.

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